K022835

NOV 1 2002

510 (k) Summary

Device Trade or Proprietary Name: Stephens Disposable Forceps

Device Common or Usual Name or Classification: Ophthalmic Forceps

Classification Name/Product Code(s): 86HNR, Ophthalmic Forceps

Predicate Devices: Katena Ophthalmic Forceps, Storz Ophthalmic Forceps, Rhein Ophthalmic Forceps, Stephens Ophthalmic Forceps

Device Description: A single use ophthalmic device designed to manipulate eye tissues or muscles.

Device Use: Designed for single use manipulating of eye tissues or muscles in various ophthalmic procedures.

Classification: Class I

Comparison to Predicate Devices:

Device Name	Katena Ophthalmic Forceps	Storz Ophthalmic Forceps	Rhein Ophthalmic Forceps	Stephens Ophthalmic Forceps
Intended Use	Manipulation of eye tissues or muscles in various ophthalmic procedures	Manipulation of eye tissues or muscles in various ophthalmic procedures	Manipulation of eye tissues or muscles in various ophthalmic procedures	Manipulation of eye tissues or muscles in various ophthalmic procedures
Performance	Compatible	Compatible	Compatible	Same
Material	420 Stainless Steel	420 Stainless Steel	420 Stainless Steel	420 Stainless Steel & Polystyren

Performance Tests and Conclusions:

1.0 Dimensional Equivalency Test – The teeth measurements of the forceps were substantially equivalent to the measurements of the predicate devices listed above.

2.0 Manipulation Tests-The mechanism and holding ability of the Stephens forceps were found to perform as well as the predicate devices.

Clinical Tests: None
Adverse S & E Information: None

A. Johnson
Archana Johnson

10-4-02
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 2002

Stephens Instruments
c/o Ms. Archana Johnson
2500 Sandersville Road
Lexington, KY 40511

Re: K022835
Trade Name: Stephens Disposable Forceps
Classification Regulation Number: 886.4350
Regulatory Class: I
Product Code: HNR
Dated: August 21, 2002
Received: August 27, 2002

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number : K022835

Device Name : Ophthalmic Forceps

Indications for Use :

Forceps for single use designed for the manipulation of tissue or muscles in various ophthalmic procedures.

Deborah Falls

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K022835

Prescription Use ✓
(Per 21 CFR 801.109)